K111178

510k Summary

July 13, 2011

SEP 12 2011

Trade Name: JUELLCure Soft

Common Name: soft impression material

Company Contact:

John Roderick, Operations Manager
Juell Dental
2401 N. Commerce
Ardmore, OK 73401
(580) 798-4414

Device Classification: resin, denture, relining, rebasing

Device CFR Section: 21 CFR 872.3760

FDA Device Class: Class II

FDA Product Code: EBI

Classification Panel: Dental

Device Description: JuellCure Soft is a self-curing, silicone-based and permanently soft relining material for removable dentures.

Indications for Use:

JUELL Soft Cure is intended for use as a permanent soft relining for total and partial dentures

- To relieve pressure from pressure points
- To dam the palatal vibrating line
- In cases of flabby ridge and/or insufficient adhesion
- To cushion sharp-edged alveolar processes

Testing

The working time and setting time were determined for the Soft Cure base, catalyst, glazing base, and glazing catalyst. The surface hardness (Shor hardness A), and adhesion to dentures was determined.

Predicate Device: Ufi Gel SC, K974772, VOCO GmbH, Germany

K111178

Substantial Equivalence

The material composition of Ufi Gel SC and Juel Soft Cure are very similar. The indications for use are the same. The surface hardness, adhesion time and working time are the same.

Function	JUELL Soft Cure	Ufi Gel SC
Monomer Matrix	70 – 80 %	70 – 80 %
Rheologic Modifier	15 – 30 %	15 – 30 %
Catalyst	0,1 – 0,5 %	0,1 – 0,5 %
Monomer Matrix	70 – 80 %	70 – 80 %
Rheologic Modifier	15 – 30 %	15 – 30 %
Colorant	<0.1 %	<0.1 %
Co-Monomer	5 – 10 %	5 – 10 %

Function	JUELL Soft Cure	Ufi Gel SC
Monomer Matrix	80 – 90 %	80 – 90 %
Rheologic Modifier	10 – 20 %	10 – 20 %
Catalyst	0,1 – 0,5 %	0,1 – 0,5 %
Monomer Matrix	60 – 70 %	60 – 70 %
Rheologic Modifier	20 – 30 %	20 – 30 %
Stablizer	8 – 15 %	8 – 15 %

Function	JUELL Soft Cure	Ufi Gel SC
Monomer Matrix	70 – 85 %	70 – 85 %

K111178

Rheologic Modifier	15 – 20 %	15 – 20 %
Stabilizer	0,1 – 0,5 %	0,1 – 0,5 %
Co-Monomer	2 – 5 %	2 – 5 %

Test Item	JUELL Soft Cure	Ufi Gel SC
Surface hardness (Shore hardness A)	26.3	26.3
Adhesion to dentures	190 N	190 N
Working time	201 s	201 s

JuellCure Soft is substantially equivalent to Ufi Gel SC in regards to indications, composition, and testing results.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Juell Dental
C/O Ms. Angela Blackwell
Senior Consultant
Biologics Consulting Group
2401 N Commerce
Ardmore, Oklahoma 73401

SEP 12 2011

Re: K111178
Trade/Device Name: JuellCure Soft Impression Material
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, or Rebasing Resin
Regulatory Class: II
Product Code: EBI
Dated: August 30, 2011
Received: September 1, 2011

Dear Ms. Blackwell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

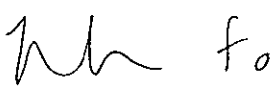
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _K111178

Device Name: ___JuellCure Soft Impression Material_____

Indications for Use:

JUELLCure Soft is indicated for use as a permanent soft relining for total and partial dentures:

- to relieve pressure from pressure points
- to dam the palatal vibrating line
- in cases of flabby ridge and/or insufficient adhesion
- to cushion sharp-edged alveolar processes

Prescription Use ____x___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K111178